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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/662,783      | 09/12/2000  | Richard A. Shimkets  | 15966-577 (CURA-77) | 3145             |

30623 7590 04/23/2003  
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
AND POPEO, P.C.  
ONE FINANCIAL CENTER  
BOSTON, MA 02111

EXAMINER

JIANG, DONG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/23/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 09/662,783      | SHIMKETS ET AL. |
|                              | Examiner        | Art Unit        |
|                              | Dong Jiang      | 1646            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 27 February 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,2,40 and 66 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,2,40 and 66 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED OFFICE ACTION**

Applicant's amendment in paper No. 12, filed on 27 February 2003 is acknowledged and entered. Following the amendment, claims 3-39 and 41-65 are canceled, claims 1 and 2 are amended, and claim 66 is added.

Currently, claims 1, 2, 40 and 66 are pending, and under consideration.

### **Withdrawal of Objections and Rejections:**

The objection of the specification is withdrawn in view of applicant's amendments.

All objections and rejections of claims 3-5 are moot as the applicant has canceled the claims.

The scope rejection of claims 1, 2 and 40 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendment and argument.

The rejection of claims 1, 2 and 40 under 35 U.S.C. 112, first paragraph for lack of written description is withdrawn in view of applicant's amendment.

### **Objections and Rejections under 35 U.S.C. §101 and §112:**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 66 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to a polypeptide dimer, which reads on a product of nature and thus, is unpatentable to applicant. It is suggested that applicant use the language "isolated" or "purified" in connection with the polypeptide to indicate the hand of the inventor. See MPEP 2105.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 40 remain rejected, and the new claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, remains indefinite because it is unclear what "growth factor activity" refers to, and the specification does not define such term. As there are many growth factors having diverse activities, the metes and bounds of the claim, therefore, cannot be determined.

Claim 2 remains indefinite because it is unclear how the polypeptide of the claim can be both SEQ ID NO:4 (residues 239-370 of SEQ ID NO:2) as it depends from claim 1, and residues 247-370, 247-338, or 339-370 of SEQ ID NO:2.

Claim 66 is indefinite because it is unclear whether the polypeptide dimer is homodimer or heterodimer. The metes and bounds of the claim, therefore, cannot be determined.

The remaining claim is rejected for depending from an indefinite claim.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 40 remain rejected under 35 U.S.C. 102(a) as being anticipated by Eriksson et al., WO200027879, for the reasons set forth in the last Office Action, paper No. 10, mailed on 27 August 2002, at page 9.

Applicants argument, filed on 27 February 2003 (paper No. 12) has been fully considered, but is not deemed persuasive for reasons below.

At page 7 of the response, the applicant argues that claim 1 recites SEQ ID NO:4, which is a 132 amino acid polypeptide corresponding to amino acids 239-370 of SEQ ID NO:2 of the present application, and is a piece of, and is not the exact same sequence as SEQ ID NO:6 or 8 of the prior art reference. This argument is not persuasive because the term "comprising" used in claim 1 of the present invention is an open term, indicating possibly additional sequence. As such, the limitation of the present claim 1 encompasses the prior art sequence, and therefore the

cited sequence anticipates the claims. If the specific fragments are intended in the claim, the language such as "consisting of" is suggested.

**Conclusion:**

No claim is allowed.

**Advisory Information:**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

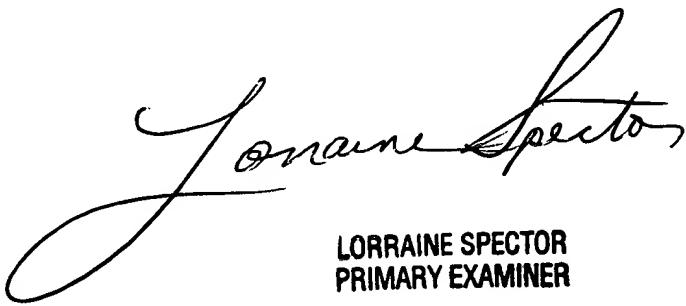
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
4/14/03



LORRAINE SPECTOR  
PRIMARY EXAMINER